

**REMARKS**

**I. Claim Amendments**

Claims 1-4, 12 and 30-34 are canceled.

Claims 5 and 7 are amended to recite a crystal of a non-solvate of (3R)-1-butyl-2,5-dioxo-3-((1R)-1-hydroxy-1cyclohexylmethyl)-9-(4-(4-carboxyphenoxy)phenylmethyl)-1,4,9-triazaspiro[5.5]undecane hydrochloride.

Claims 9 and 10 are amended to change their dependencies in view of the cancellation of claims 1 and 2.

Claims 22 and 24 are amended to recite that the crystal of a non-solvate of (3R)-1-butyl-2,5-dioxo-3-((1R)-1-hydroxy-1cyclohexylmethyl)-9-(4-(4-carboxyphenoxy)phenylmethyl)-1,4,9-triazaspiro[5.5]undecane hydrochloride has a powdery X ray diffraction spectrum shown in Fig. 1 and an IR absorption spectrum shown in Fig. 3.

Claims 24 and 26 are amended by replacing the term "C<sub>1-4</sub> alcohol" with "C<sub>1-4</sub> alkyl alcohol" to correct a translation error.

New claims 35 and 36 are added, which are directed to the melting point of the crystal.

Support for the claim amendments is found, for example, in the original claims.

No new matter is presented

**II. Drawings**

The Examiner has not indicated acceptance of the replacement drawings filed on March 21, 2006. Applicants respectfully request the Examiner to indicate that the drawings have been accepted in the next Action for the required.

**III. Response to Claim Rejections - 35 U.S.C. §112**

Claims 31-33 are rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirement.

Without conceding the merits of the rejection, claims 31-33 are canceled herein, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

**IV. Response to Claim Rejections - 35 U.S.C. §102**

Claims 30-33 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Redfield (U.S. 2006/0099170).

Without conceding the merits of the rejection, claims 30-33 are canceled herein, thereby obviating the rejection.

Accordingly, Applicants respectfully request withdrawal of the rejection.

**V. Claim Rejections - 35 U.S.C. §103**

Claims 1-4, 9-12, 22, 28 and 29 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Redfield (U.S. 2006/0099170).

Without conceding the merits of the rejection, claims 1-4 and 12 are canceled herein, thereby rendering the rejection as to these claims moot.

As applied to the present claims, Applicants respectfully traverse the rejection and submit that Redfield does not teach or suggest the present invention.

The present invention is directed to a crystal of AK-602.

In Redfield, AK-602 is listed as an example of a CCR5 antagonist or viral infection inhibitor. Redfield does not describe any structure, feature or production method for AK-602. Therefore, Redfield does not provide an enabling description such that one of ordinary skill in the art can carry out crystallization of the compound of the present invention. Additionally, Redfield does not motivate crystallization of the compound of the present invention. For at least these reasons, the present invention is not anticipated nor rendered obvious by Redfield.

Accordingly, Applicants respectfully request withdrawal of the rejection.

## **VI. Double Patenting**

1. Claims 30-32 are rejected under 35 U.S.C. §101 as allegedly claiming the same invention as that of claims 3 and 4 of prior U.S. Patent 7,053,090.

2. Claims 1-4, 9-12, 22, 28 and 29 are rejected on the ground of non-statutory obviousness-type double patenting as allegedly being unpatentable over claims 1 and 2 of U.S. Patent 7,053,090. The Examiner asserts that the claims are not patentably distinct from each other because in absence of XRD data or IR absorption spectrum data for specific crystalline form of this compound, it would have been obvious to one skilled in the art to prepare any crystalline form of this compound.

Without conceding the merits of the rejection, claims 1-4, 12, and 30-32 are canceled, thereby rendering the rejections as to these claims moot.

Applicants note that the '090 patent does not describe the features or state of the present claimed compounds at all. It cannot be determined whether the compounds of the '090 patent are amorphous, solvate or non-solvate. Furthermore, with regard to the description of a crystal,

recrystallization is described only as an example of a purification method in the '090 patent, while crystallinity of the compound is not described. Therefore, motivation of synthesis of a crystal of a non-solvate of the compound in the present application cannot be found in the disclosure of the '090 patent. Additionally, with regard to the method for producing the crystal, there is no description such that the person skilled in the art can obtain crystal of non-solvate.

Furthermore as described in the "Background of the Art", the compound of the present invention was obtained in the state of a solvate by the usual method. Therefore, further investigation is necessary to obtain a non-solvate. Accordingly, the crystal of the present invention is not anticipated nor rendered obvious by the claims or disclosure of the '090 patent.

Withdrawal of the rejection is respectfully requested.

#### **VII. Allowable Subject Matter**

Claims 5-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 5 and 7 are amended and rewritten into independent form, thereby obviating the rejection. Claims 6 and 8 depend from claims 5 and 7 respectively and are patentable for at least the same reasons.

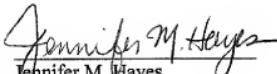
#### **VIII. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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